

REMARKS

Claims 1-37 are currently pending, with claims 23-36 being withdrawn from consideration. Claim 37 has been added to depend from claim 4 and is directed to the sheath polymer consisting of a protein selected from the group of collagen, gelatin, or serum albumin. Claims 1-16 have been amended to replace the term “means” with “structure” to more clearly define the claimed composition. Claim 4 has been amended to remove the groups “collagen, gelatin, serum albumin”. Claim 15 had been amended to correct the dependency of the claim to claim 14. Claims 17-22 have been amended to correct the dependency of the claims to claim 16. The title of the application has been amended to “Filamentary means for introducing agents into tissue of a living host”. An abstract has also been added to the application. Applicants respectfully submit that no new matter has been added to the application by these amendments.

The specification of the application is objected to as not containing an abstract. The application has been amended to include an abstract.

Claims 1-22 have been rejected. Claims 1-22 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite as it is not clear what it meant by “filamentary means”. Claim 4 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite for having a broad limitation and a narrow limitation falling under the broad limitation, in the same claim. Claim 15 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite as not having antecedent basis for the term “open pores”. Claims 14-15 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite with regard to the term “large enough”. Claims 17-22 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for improperly depending from a product claim. Claims 1-5, 11-14, 16, 17, 20 and 21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,486,593 issued to Tang et al. (hereinafter “Tang”). Claims 1-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Tang in view of U.S. Patent No. 6,027,744 issued to Vacanti et al. (hereinafter “Vacanti”) and U.S. Patent No. 4,104,195 issued to Ley et al. (hereinafter “Ley”). Applicants respectfully traverse these rejections for at least the following reasons.

Rejection of claims 1-22 under 35 U.S.C. § 112, second paragraph

The Office Action rejected claims 1-22 under 35 U.S.C. § 112, second paragraph as being indefinite as it is not clear what it meant by “filamentary means”. Claims 1-16 have been amended to replace the term “means” with “structure” to more clearly define the claimed composition. Applicants submit that claims 1-22, as amended herein, clearly define the claimed composition and respectfully request that the rejection to the claims on this ground be withdrawn.

Rejection of claim 4 under 35 U.S.C. § 112, second paragraph

The Office Action rejected claim 4 under 35 U.S.C. § 112, second paragraph as being indefinite for having a broad limitation and a narrow limitation falling under the broad limitation, in the same claim. Applicants have amended claim 4 to remove the narrower limitations of “collagen, gelatin, serum albumin” and have added these limitations in new dependent claim 37. Applicants submit that claim 4 as amended herein, clearly defines the claimed composition and respectfully request that the rejection to the claim on this ground be withdrawn.

Rejection of claim 15 under 35 U.S.C. § 112, second paragraph

The Office Action rejected claim 15 under 35 U.S.C. § 112, second paragraph as being indefinite as not having antecedent basis for the term “open pores”. Claim 15 had been amended to correct the dependency of the claim to claim 14. Applicants submit that claim 15, as amended herein, has proper antecedent basis for the term “open pores” and respectfully request that the rejection to the claim on this ground be withdrawn.

Rejection of claims 14-15 under 35 U.S.C. § 112, second paragraph

The Office Action rejected claims 14-15 under 35 U.S.C. § 112, second paragraph as being indefinite with regard to the term “large enough”. Claim 14 contains the limitation of open pores in the porous sheath that are “large enough to admit the agent”. Claim 15 contains the limitation that the open pores of the porous sheath are “large enough to admit molecules ranging in molecular weight from about 500 to about 100,000 Daltons.” When a practitioner of ordinary skill in the art is using the presently claimed filamentary composition to deliver an agent, the practitioner would be knowledgeable of the specifics of the agent

being delivered, including the molecular size of such an agent. Page 10, lines 10-20 of the specification delineate that the pores of the sheath are designed to admit the agent into the porous sheath to allow it the agent to be delivered into those in which the filamentary agent is attached or imbedded. One of ordinary skill in the art would clearly understand the definition "large enough" to mean that the pore is of a size equal or greater than the size of the agent to be admitted into the sheath. Applicants respectfully submit that in view of the teachings of the specification, one of ordinary skill in the art would clearly understand the meaning of the term "large enough" and request that the rejection of the claims under this ground be withdrawn.

Rejection of claims 17-22 under 35 U.S.C. § 112, second paragraph

The Office Action rejected claims 17-22 under 35 U.S.C. § 112, second paragraph as being indefinite for improperly depending from a product claim. Claims 17-22 have been amended to correct the dependency of the claims to claim 16. Applicants submit that claims 17-22 properly depend from a method claim and respectfully request that the rejection to the claims on this ground be withdrawn.

Rejection of claims 1-5, 11-14, 16, 17, 20 and 21 under 35 U.S.C. § 102(b) over Tang

The Office Action has rejected claims 1-5, 11-14, 16, 17, 20 and 21 under 35 U.S.C. § 102(b) as being anticipated by Tang. The Manual of Patent Examining Procedure "MPEP" § 2131 states that, in order to anticipate a claim, a reference must teach every element of the claim:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)."

Applicants respectfully submit that the Tang reference has failed to disclose each and every element of the present invention.

Claims 1 and 16 are each independent claims. Claims 2-5 and 11-14 depend directly or indirectly from claim 1; while, claims 17, 20 and 21 depend from claim 16. Claim 1 is directed to a filamentary composition comprising a filament comprising a solid core and a

porous sheath, wherein the porous sheath comprises a bioabsorbable sheath polymer which coats at least a portion of the solid core. (Language of claim 1, underlined). Claim 16 is directed to a method of making a filamentary composition, wherein a bioabsorbable polymer and a pore-forming agent are coated onto a filamentary solid core, and the pore-forming agent removed or decomposed. (Language of claim 16, underlined). Applicant respectfully submits that Tang fails to teach the porous sheath coating element common to the two independent claims cited above.

The Tang reference is directed towards biocompatible devices comprised of bioabsorbable polymers, with "fillers, binders, additives, and components" which can be made of a variety of different substances listed therein. (See Tang, col. 19, lines 27-28). However, nowhere in Tang it is disclosed that a porous sheath is applied to a fiber. While the Tang reference discloses bioabsorbable polymer fibers that optionally can be coated with other bioabsorbable polymers (See Tang, col. 7, lines 28-36), it does not teach or suggest the coating of the a filamentary solid core with a porous sheath coating. Instead it is stated that porous fibers can be made with the use of foaming agents. Tang discloses that "the fibers of this invention may also be porous. These fibers can be formed by the addition of fillers, binders, additives and components which were added to the biopolymer before or during fiber formation..." (See Tang, col. 7, lines 17-26). Nowhere does it state that a sheath containing fillers, binders, additives and components should be coated on a fiber after fiber formation.

The Office Action also states that the Tang reference discloses that "polymers contain drugs such as growth factor and can be coated on the porous layer". (See Office Action page 5). The Office Action cites col. 19, lines 1, 10-15, 27-30 of Tang as supporting this assertion. These passages, as well as the rest of the Tang reference, however, fail to disclose any such "porous layer". It appears the Examiner is confusing the coatings that can be applied, "plasticizers, lubricants, antioxidants, stabilizers of all kinds such as stabilizers for UV radiation, heat, moisture, and the like as well as drugs for treatment of certain disorders or diseases and growth factors such as those for nerve and bone, and growth hormones in general." (See Tang col. 19, lines 16-21), with the "fillers, binders, additives and components ...removed...so that a porous or semi-porous system can be obtained." (See Tang col. 19, lines 27-30). The "porous or semi-porous system" refers to the entire biopolymer device taught by Tang, not just the coating.

As the Tang reference fails to disclose all of the elements of claims 1 and 16, specifically the element of a porous sheath coating, Applicants respectfully submit that the Tang reference fails to anticipate claims 1 and 16. As claims 2-5, 11-14, 17, 20 and 21 depend directly or indirectly from either claim 1 or claim 16, these claims contain all of the elements and limitations of claims 1 and 16. Applicants submit that these claims are also not anticipated by the Tang reference for the reasons stated above and for the additional limitations presented therein.

Rejection of claims 1-22 under 35 U.S.C. § 103(a) over Tang in view of Vacanti and Ley

The Office Action has rejected claims 1-22 under 35 U.S.C. § 103(a) as being unpatentable over Tang in view of Vacanti and Ley. MPEP § 2141.03 states:

“To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 USPQ 494, 496 (CCPA 1970).”

Applicants respectfully submit that the Office Action has failed to put forth a *prima facie* case of obviousness, as the combined references of Tang, Vacanti and Ley fail to disclose all of the limitations of the present invention.

As discussed above, independent claim 1 is directed to a filamentary composition comprising a filament comprising a solid core and a porous sheath, wherein the porous sheath comprises a bioabsorbable sheath polymer which coats at least a portion of the solid core. (Language of claim 1, underlined). Claim 16 is directed to a method of making a filamentary composition, wherein a bioabsorbable polymer and a pore-forming agent are coated onto a filamentary solid core, and the pore-forming agent removed or decomposed. (Language of claim 16, underlined). Applicant respectfully submits that none of the cited references teach or suggest the limitation of a porous sheath coating a filamentary solid core.

As discussed above, the Tang reference discloses the creation of porous fibers by the use of foaming agents. The reference does not teach or suggest coating a solid core fiber with a porous sheath.

The Vacanti reference contains no teaching or suggestion of any porous bioabsorbable polymer. While the Vacanti reference discloses the use of fibers to be wove into a mesh that

“form a porous support structure” (See Vacenti co. 6, line 17-18), it does not teach or suggest coating the individual fibers themselves with a porous bioabsorbable sheath.

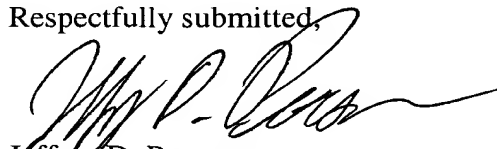
The Ley reference, while disclosing the production of porous articles by the use of various blowing agents, does not teach or suggest the use of a porous bioabsorbable sheath to coat a filamentary solid core.

As neither the Tang, Vancenti or Ley references, alone or in combination, teach or suggest the limitation of a porous sheath coating a filamentary solid core, Applicants respectfully submit that the Office Action has failed to set forth a *prima facie* case of obviousness with respect to claims 1 and 16. As the remaining claims of the application depend directly or indirectly from either claim 1 or claim 16, these claims contain all of the elements and limitations of claims 1 and 16. Applicants submit that the Office Action has failed to set forth a *prima facie* case of obviousness with respect these claims for the reasons stated above and for the additional limitations presented therein.

SUMMARY

Based on the foregoing, Applicants respectfully submits that Claims 1-22 and 37 are in condition for allowance. A favorable action is thereon respectfully requested. Should the Examiner feel that any other point requires consideration or that the form of the claims can be improved, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



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